

# QAM 12030: iTRACK PROCEDURES AND RISK **ASSIGNMENT**

# **Revision History**

Author	Description of Change	<b>Revision Date</b>
Jemila Adetunji	Procedure updated to reflect upgrades to the iTrack system,	January 2015
Kathy Zappia	updated risk assignment tables, and clarification of iTrack	
	usage.	
Rafael Coll	This chapter combines FESHM 1010.2 and FESHM 1010.3	November 2013
	into one chapter and replaces frESHTRK with iTRACK as	
	the sole issues management system for Fermilab. FESHM	
	chapters on frESHTRK Procedures 1010.2 and 1010.3 are	
	cancelled upon publication of this chapter.	

WARNING: This manual is subject to change. The current version is maintained on the ESH Section website.





# **TABLE OF CONTENTS**

1.0	INTRODUCTION	3
2.0	DEFINITIONS	3
3.0	RESPONSIBILITIES	4
2.1	Formalish Ovelity Assurance Manager	,
	Fermilab Quality Assurance Manager	
3.2	Division/Section/ (D/S) Heads and Project Managers	4
4.0	PROGRAM DESCRIPTION	5
4.1	Item Definitions	
4.1	item Definitions	
5.0	PROCEDURES	6
5.1	iTrack uses	,
5.1		
5.1		
	iTrack Users	
5.2 5.2		
5.2 5.2	,	
	iTrack Procedures	
5.3 5.3	·	
5.3		
5.3		
5.3		
5.3	3.6 Complete and Close Action Plan or Response	11
5.3	O .	
5.3	3.8 Verification Process	11
5.4	Risk Assessment Codes	13
5.5	Causal Analysis	14
6.0	REFERENCES	14
7.0	TECHNICAL APPENDIX A	4 F
7.0	I ECHNICAL APPENDIA A	15
8.0	APPENDIX B DEFINITIONS OF ACTIVITIES TRACKED IN ITRACK	17



#### INTRODUCTION

iTrack is a database used to document and facilitate the resolution of items of any nature arising from formalized activities where reports are typically generated.

Experience has shown that items found cannot all be rapidly and completely addressed using available resources; therefore it is prudent first to address those presenting the greatest risk. This chapter describes the uses for iTrack, the procedures for using iTrack, and the procedures for assigning risk values to items entered into iTrack.

This chapter follows Fermilab's policy on issues management.

#### 1.0 **DEFINITIONS**

#### Assessment

A review, evaluation, surveillance, or audit where a systematic approach is used to evaluate processes, systems or services to determine compliance to specified requirements and effectiveness; with the goal of identifying areas of non-compliance and best practice. An assessment usually results in corrective actions where appropriate resolution is required.

#### • Corrective Action

The action taken to eliminate the cause of a detected non-conformance or other undesirable situation. *Note: There can be more than one cause for nonconformity. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.* 

#### Hazard Severity

An assessment of the potential consequences, defined by degree of injury, occupational illness, environmental impact, or property damage that is likely to occur as the result of a deficiency. This determination is subjective in nature.

#### • Item

Defined as non-conformances, findings, opportunities for improvement, recommendations, best practices, and management concerns that are the outputs to reviews that are tracked in iTrack.

#### Mishap Probability

The probability that a hazard will result in an incident based on an assessment of such factors as location, exposure, and affected population. This determination is subjective in nature.

#### Notable or Observation

Worthy of note: significant, interesting, or unusual enough to deserve attention or to be recorded.

### • Preventive Action



### Fermilab Quality Assurance Manual

QAM 12030 January 2015

The action taken to eliminate the cause of a potential non-conformance or other undesirable potential situation.

Note: There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

#### Risk Assessment Code

The degree of risk associated with a deficiency that combines the elements of hazard severity and mishap probability.

### • Root Cause Analysis

An identified reason for the presence of a defect or problem. The most basic reason, which if eliminated, would prevent recurrence. The source or origin of an event. Root cause is also known as the system cause.

### 2.0 RESPONSIBILITIES

### 2.1 Fermilab Quality Assurance Manager

- Managing the iTrack database and providing training for its use.
- Ensuring that the results of assessments conducted by organizations external to Fermilab are entered.
- Performing periodic review of the contents of iTrack to check on the appropriateness and status of follow-up actions and to identify trends and lessons learned.
- Reviewing periodic trending and analyses to determine if associated programs need to be redirected, to verify that root causes are being adequately addressed, and lessons generated.

# 2.2 Chiefs, Division/Section (D/S) Heads and Project Managers

- Entering the results of internal assessments, inspections, and Tripartite assessments, including all findings, nonconformities, observations, opportunities for improvement, recommendations, and best practices (open and closed), are entered into iTrack. Entering the results of project-specific reviews (Critical Decision, DOE, Lehman or otherwise), including all recommendations and their resolution into iTrack.
- Implementing corrective and preventive actions for issues and closing them out in iTrack.
- Periodically reviewing the contents of iTrack to check on the appropriateness and status of follow-up actions, and to identify trends.
- Verifying that corrective and preventive actions were implemented as reported. All Findings and Non-Conformances with a Risk Code of 1 or 2 will have their corrective and preventive actions verified within 90 days of reported closure. Ten percent of Findings and Non-Conformances with a Risk Code of 3 will have their corrective and preventive actions verified. Documentation of the verification process shall be done quarterly through iTrack by the Senior Safety Officers (SSOs) and the ESH&Q-Quality Assurance group.
- Ensuring that the effectiveness of implemented corrective and preventive actions is reviewed and documented within iTrack.



### 3.0 PROGRAM DESCRIPTION

iTrack is a database that is used at Fermilab to support process performance monitoring and followup of associated items regardless of discipline. In particular, iTrack plays a key role in monitoring the status of Fermilab's self-assessment program and other issues.

For consistency, iTrack calls activities that generate items "reviews". The term "item" refers to findings, non-conformances, management concerns, recommendations, opportunities for improvement, and best practices that are the output of these activities. The definitions and requirements for each item type are defined below.

#### 3.1 Item Definitions

### • Non-Conformance / Finding:

The nonfulfillment of a specified requirement. A finding or nonconformance can be found in a service, product, process, from a supplier, policy, or from a system. The specified requirements can be identified from a regulatory body or internal policy or procedure.

### Requirements in iTrack:

- Perform Risk Analysis
- o Identify root cause (through Causal Analysis or HPI)
- o Corrective or Preventive Actions identified

### • Management Concern:

An issue that management has identified as a concern requiring actions to be taken to ensure risk associated with that issue is mitigated.

#### Requirements in iTrack:

- Perform Risk Analysis
- o Identify root cause (through Causal Analysis or HPI)
- Corrective or Preventive Actions identified

#### • Recommendation:

A suggestion or proposal from the Reviewer as to the best course of action to be taken on an identified topic.

### Requirements in iTrack:

- o Response is required
- o Risk Analysis is Optional
- Do not require a root cause be identified

#### • Opportunity for Improvement

Suggestions identified on how to improve the identified topic.



### Requirements in iTrack:

- o Response is required
- Risk Analysis is Optional
- o Does not require a root cause to be identified

#### • Best Practice

Method or technique that has consistently shown results superior to those achieved with other means, and that may be used as a benchmark.

#### Requirements:

- Best Practices entered into iTrack do not require a root cause to be identified
- o Best Practices do not require any Corrective/Preventive Actions or Responses
- o They are entered into iTrack to be shared for information only

### 4.0 PROCEDURES

#### 4.1 iTrack uses

#### 5.1.1 Reviews and Items tracked in iTrack

iTrack is used to track items from reviews where reports are typically issued. Reviews, where reports are typically issued, can include the following (for definitions of reviews listed, see Appendix B):

- DOE Activities
- Director's Triennial assessments
- External Reviews (ISO/OHSAS, IEPA, USDOT etc.)
- Incidents or Events (CAIRS, ORPS, Near Miss, etc.)
- Formal (organized) ES&H Inspections and Walkthroughs, including HPR Inspections
- Planned Self-Assessments (Quality, D/S/P, Tripartite, etc.)
- Fermilab Internal Reviews (Director's Reviews, FRA / CAS Reviews, etc.)
- Review findings on projects managed by other institutions where Fermilab is just a collaborator

#### 5.1.2 Reviews and Items NOT tracked in iTrack

Items resulting from activities where information is sensitive, another formal process exists, or no formal reports are issued are tracked by individual organizational databases (and/or spreadsheets, etc.) and can include:

- Fire Department inspections, FESS inspections, items corrected by work orders, routine equipment inspections (emergency lights and exit lights not working, routine inspections of eyewash stations and showers, etc.),
- Action items or task lists from meetings,
- New employee orientation tours,





- Items found randomly while performing normal work activities. These items should be reported through the normal management chain,
- Personnel related issues such as tracking attendance,
- Items from Internal Audit or Financial Reviews where there is sensitive financial information.
- Lessons Learned (to be entered into the established Lessons Learned DB per QAM 12010 Contractor Assurance/Lessons Learned Program & Procedures.).

#### 4.2 iTrack Users

iTrack has 3 levels of users. Each level of user has unique privileges within the system. Each level is defined below.

#### **5.2.1** iTrack Administrator

An iTrack Administrator has unique privileges in iTrack to ensure the system is operating properly for Data Entry and General Users.

- Ability to assign Data Entry rights to General Users
- Ability to enter and update reviews and items for any D/S/P
- Maintains nomenclature in Oracle
- Maintains Oracle iTrack data specific to
  - o Action Plan / Response Types
  - External Agencies
  - Item Types
  - o Hazard Severities & Mishap Probability Risk Code Map
  - Project List
  - o Review Categories
  - Unsafe Codes
- Maintains iTrack email distribution for
  - High Risk Code notification
  - Corrective Action Verification

### 5.2.2 iTrack Data Entry User

An iTrack Data Entry User has data entry privileges in iTrack specific to the organization they are assigned to. Some Data Entry Users may be assigned to multiple organizations (Divisions / Sections or Projects).

A Data Entry User can

- View all open reviews performed on their Division, Section or Project
- Enter new reviews
- Enter new items
- Edit reviews
- Edit items
- Close items
- Run reports
- Query the database
- Extract data to Excel



### 5.2.3 iTrack Responsible Party / General User

A responsible party is someone who has been assigned responsibility for an item in iTrack. They have limited privileges in iTrack that include

- Query the database
- Extract data to Excel
- Responsible party delegate responsibility to other parties
- Responsible party update and close items assigned to them only

#### 4.3 iTrack Procedures

Please refer to the <u>iTrack Data Entry User Guide</u> found on the <u>ESH&Q iTrack Homepage</u> for detailed instructions on how to enter reviews and items into iTrack, and for detailed descriptions of the data entry fields and for information on which fields are required and optional for data entry into the system.

NOTE: Items that cross D/S/P organizational lines shall be negotiated with all applicable D/S/P heads in advance of entering data into iTrack.

The following iTrack steps define 3 key pieces of information for each individual step:

- Responsible: This is the person responsible for executing the step.
- Action: Detailed actions to be taken by the responsible person executing the step.
- <u>Communication</u>: Explanation of the automatic communication iTrack sends when that step is completed, including whom the recipients are.

### 5.3.1 Review complete, enter details into iTrack

- <u>RESPONSIBLE</u>: Person or Organization that performed or sponsored the Review the designated Data Entry User.
- <u>ACTION</u>: A Review occurs and the information needed to enter the Review into iTrack is gathered. Information entered into iTrack about the Review includes:
  - Review title and description
  - Dates the review occurred
  - Who was involved in the review (participants)
  - Link to final report if applicable and available

The following 6 Review Categories exist in iTrack:

- External Reviews
- DOE Activities
- Incidents or Events
- ES&H Activities
- Internal Activities



- Self-Assessments
- COMMUNICATION: None

### 5.3.2 Entering new Items

- <u>RESPONSIBLE</u>: Person or Organization that performed or sponsored the Review the designated Data Entry User.
- <u>ACTION</u>: Items that are the output of the Review are entered into iTrack and assigned to the appropriate person responsible for resolving the item also known as the Responsible Party. Information in iTrack about the Items includes:
  - Title and description of the item
  - What type of item was found (see section 4.0 for definitions of each Item type)
    - Non-Conformance / Finding
    - Management Concern
    - Opportunity for Improvement
    - Recommendation
    - Best Practice
  - Where and when the item was found
  - Risk associated with that item if applicable(see section 4.0 for a list of items this applies to, and the Technical Appendix for how to perform a Risk Analysis)
  - What management system the item is associated with
  - Responsible Party assigned to the item
  - Due date
- <u>COMMUNICATION</u>: Responsible Party, CC direct manager, CC Distribution List.
  - Once the item has been submitted to iTrack, an email confirmation will be sent automatically from iTrack to the Responsible Party, with CC to their direct Manager, and anyone listed in the Distribution List section of the data entry form.
  - The Responsible Party and direct Manager will receive email notification of any updates made to the item, and the Distribution List will only receive email notification of the item's open and closure.
  - The email notification will also include instructions and references to help guide the Responsible Party in updating items assigned to them.

#### **5.3.3** Delegating Responsibility

- RESPONSIBLE: Responsible Party assigned to the Item
- <u>ACTION</u>: The Responsible Party has the 3 options to assign the action to someone else (delegate responsibility)
  - Solely to one other person,
  - To multiple people, or





• Keep responsibility with themselves and not delegate responsibility.

The Responsible Party must know:

- 5-digit Fermilab IDs of the people they are delegating to or sharing responsibility with
- Due dates by which items are to be completed
- <u>COMMUNICATION</u>: Any new Responsible Parties and their direct Managers will be sent an email notification notifying them of their newly assigned responsibility just as in step 5.3.2.

## 5.3.4 Determining Root Cause – if Required based on Item Type (see section 4.0)

- <u>RESPONSIBLE</u>: Responsible Parties (and identified team to assist with the task if applicable external to iTrack)
- <u>ACTION</u>: Non-Conformances, Findings, and Management Concerns all require a
  Causal Analysis to be completed to determine the actual root cause of the original issue
  found. See <u>QAM 12050 Root Cause Analysis</u> for guidelines on how to complete this
  step. This step can be completed 2 ways
  - Choosing the applicable HPI Analysis choice, or
  - Through providing a detailed description of the method chosen to determine the root cause

NOTE: A Cause needs to be identified before the Item is allowed to be closed.

• <u>Communication</u>: None

### **5.3.5** Determining Action Plan or Response

- RESPONSIBLE: All Responsible Parties assigned to Item
- <u>ACTION</u>: Depending on the type of item entered, either an Action Plan or Response should be entered into iTrack. Each Responsible Party identified determines what Action Plan or Response is appropriate to resolve their portion of the item.
  - Non-Conformances, Findings, and Management Concerns require that a CORRECTIVE or PREVENTIVE ACTION PLAN be determined and entered into iTrack.
  - Opportunities for Improvement and Recommendations require only a RESPONSE be determined and entered into iTrack.
- <u>COMMUNICATION</u>: Responsible Party and direct Manager
  - The Responsible Party and their direct Manager are automatically notified by iTrack via email that a new Action Plan or Response has been added in iTrack.



### **5.3.6** Complete and Close Action Plan or Response

- <u>RESPONSIBLE</u>: All Responsible Parties assigned to Item
- <u>ACTION</u>: Responsible Parties complete all actions required and enter this information into iTrack.
  - FOR ACTION PLANS ONLY: To be able to close the Action Plan appropriately evidence of what actions occurred needs to be entered into iTrack. Evidence can include brief descriptions of the actions taken, and hyperlinks to completed documents of evidence.
  - FOR RESPONSES ONLY: For responses, only a justification response needs to be entered into iTrack on either what was done to respond to the Opportunity for Improvement or Recommendation, or justification as to why the Opportunity for Improvement or Recommendation will not be acted upon at this time.
  - COMMUNICATION: Responsible Party and direct Manager
    - Once the ACTIONS or RESPONSES have been closed in iTrack, the Responsible Party and direct Manager will receive an automatic notification email notifying them of the closure.
    - Once ALL ACTIONS or RESPONSES have been closed by ALL Responsible Parties associated with an item, the members on the Distribution List on the original item will also receive an automatic notification email.

### 5.3.7 Closing a Review

- <u>RESPONSIBLE</u>: iTrack System
- <u>ACTION</u>: The Review will automatically close after ALL Items have been closed.
  This includes any associated Corrective or Preventive Actions, Milestones, or
  Responses, and any Responsible Parties that were added in the hierarchy chain as an
  Approver.
- <u>COMMUNICATION</u>: All Responsible Parties, direct Managers, and Participants listed on the Review Distribution List will be notified automatically via email that the Review is closed.

#### **5.3.8** Verification Process

- RESPONSIBLE: ESH&Q-Quality Assurance group and Senior Safety Officers (SSO)
- <u>ACTION</u>: Once per quarter the iTrack system randomly generates samples for verification review, and generates mandatory verification reviews for items assigned a Risk Code of 1 Critical or 2 High. Verification reviews ONLY occur for closed



FINDING, AND NON-CONFORMANCE item types. Risk Code 1 and 2 Findings and Non-Conformances are verified at 100%, and risk code 3 is verified from the sample set at 10%. The items are reviewed to determine whether or not the actions taken to resolve the original issue are Effective or Ineffective.

<u>Effective</u> – the corrective actions taken have been deemed sufficient to address the corresponding issue and no occurrences have taken place since original issue.

<u>Ineffective</u> – the corrective actions taken have been deemed insufficient to address the corresponding issues; there has been recurrences or continued perceived need for improvement.

### **QA Verification Steps:**

Quality Assurance verifies findings and non-conformances from the following review categories in iTrack:

- DOE Activities
- External Reviews
- Internal Activities
- Self-Assessments
  - 1. ESH&Q Quality Assurance will receive a reminder email from iTrack that random risk code 3 samples have been selected for verification, and all Critical and High Risk items graded 1 and 2 require verification.
  - 2. ESH&Q Quality Assurance will verify the samples to ensure all actions taken were effective. These actions can include follow-up with the original Responsible Parties to determine if actions were adequate, and review of evidence provided.
  - 3. ESH&Q Quality Assurance will make the determination whether or not the Finding or Non-Conformance was closed adequately.
  - 4. The item verification determination is updated in iTrack to show that the actions taken were either effective or ineffective, and justification text for both scenarios shall be included.
    - a. If ESH&Q QA finds any item's actions as ineffective, the item can be re-opened so that further actions can be taken to resolve the issue.

#### SSO Verification Steps:

SSOs verify findings and non-conformances from the following review categories in iTrack:

- ES&H Activities
- Incidents or Events



- 1. The SSO will receive a reminder email from iTrack that random risk code 3 samples have been selected for verification, and all Critical and High Risk items graded 1 and 2 require verification.
- 2. The SSO will verify the samples to ensure all actions taken were effective. These actions can include follow-up with the original Responsible Parties to determine if actions were adequate, and review of evidence provided.
- 3. The SSO will make the determination whether or not the Finding or Non-Conformance was closed adequately.
- 4. The item verification determination is updated in iTrack to show that the actions taken were either effective or ineffective, and justification text for both scenarios shall be included.
  - a. If the SSO finds any item's actions as ineffective, the SSO will followup with the original Responsible Parties to ensure they are aware of the outcome so that mitigation actions can be taken (only if applicable), and to avoid ineffective implementation results with future items.
  - b. The item can also be re-opened so that further actions can be taken to resolve the issue. This may only occur in specific instances where an issue is still unresolved.

#### 4.4 Risk Assessment Codes

In step 5.3.2 a risk code must be chosen to enter the item into the database (see the Technical Appendix A for guidance on how to choose a risk code). The Risk Assessment Codes identify five levels of risk (see below). In general, items should be addressed in order of highest to lowest risk. D/S/P may wish to establish specific internal guidelines for addressing this matter. However, it is recognized that there may be occasional exceptions to dealing with deficiencies in rank order due to resource limitations and scheduling difficulties. Whenever a Risk Assessment Code of 1 or 2 is entered, iTrack sends an automatic e-mail message to the Assistant Director of ESH&Q, the Director, the Chief Operating Officer, and the Chief Research Officer. Immediate measures shall be taken to reduce the risk associated with such items.

Risk	Adjective rating	
assessment		
code		
1	Critical	
2	Serious	
3	Moderate	
4	Minor	
5	Negligible	

#### 4.4.1. Risk assignment changes

Senior Safety Officers, division/section/ heads and project managers are free to change risk assignments for items resulting from internal division/section/ project assessments. However, changes to the risk assignments for external items require concurrence from the



Assistant Director of ESH&Q. Such revisions may be sought because of disagreement with reviewer-assigned values or because of actual changes in the level of risk (e.g., due to progress in addressing the item). Each request to change a risk assignment should include the item number, a justification, and the name of a person most familiar with the risk associated with the item. The changes shall be communicated in writing to the responsible division/section head(s).

### 4.4.2. Qualifications to perform risk assignment

Personnel conducting reviews should be familiar with the Technical Appendix A to this Chapter.

### 4.5 Causal Analysis

FINDINGS, NON-CONFORMANCES, and MANAGEMENT CONCERNS entered into iTrack require a cause to be identified to assure that the corrective and preventive actions taken will be effective in preventing recurrence. An HPI (Human Performance Improvement) investigation may also be required depending on the type of item identified (ORPS for example). Refer to <a href="#FESHM">FESHM</a> 3010 – Significant and Reportable Occurrences for more information and <a href="QAM 12050">QAM 12050</a> – Root Cause Analysis.

### 5.0 References

Policy on Issues Management: <a href="http://www.fnal.gov/directorate/Directors\_Policy/policies.shtml">http://www.fnal.gov/directorate/Directors\_Policy/policies.shtml</a>

iTrack Data Entry User's Guide: <a href="https://esh-docdb.fnal.gov:440/cgi-bin/RetrieveFile?docid=2598">https://esh-docdb.fnal.gov:440/cgi-bin/RetrieveFile?docid=2598</a>

iTrack General User Guide: https://esh-docdb.fnal.gov:440/cgi-bin/ShowDocument?docid=3009

FESHM 3010 – Significant and Reportable Occurrences: <a href="http://esh-docdb.fnal.gov/cgibin/ShowDocument?docid=526">http://esh-docdb.fnal.gov/cgibin/ShowDocument?docid=526</a>

QAM 12010 – Contractor Assurance/Lessons Learned Program and Procedures: <a href="http://eshdocdb.fnal.gov/cgi-bin/ShowDocument?docid=2496">http://eshdocdb.fnal.gov/cgi-bin/ShowDocument?docid=2496</a>

QAM 12050 – Root Cause Analysis: http://esh-docdb.fnal.gov/cgi-bin/ShowDocument?docid=2687



#### 6.0 **Technical Appendix A**

# iTrack PROCEDURES DETERMINING THE RISK ASSESSMENT CODE FOR A FINDING, NON-CONFORMANCE, OR MANAGEMENT CONCERN

- 1. Estimate the Hazard Severity as Critical, High, Medium, Low, or Minimal using Table 1 below. Consider the worst potential consequence that is likely to occur as a result of the deficiency.
- 2. Estimate the Mishap Probability as A, B, C, D, or E using Table 2 below. This should be based on an assessment of such factors as location, exposure in terms of cycles or hours of operation, and affected population. Other circumstantial factors that should be considered include the following:
  - Number of workers exposed.
  - Frequency of exposure or duration of employee overexposure to contaminants.
  - Employee proximity to the hazardous conditions.
  - Use of appropriate personal protective equipment (PPE).
  - Medical surveillance program.
  - Other pertinent working conditions.
- 3. Use Table 3 to determine the Risk Assessment Code from the Hazard Severity and Mishap Probability estimated above.

TABLE 1.

TABLE 1.					
			HAZARD SEVERITY	T	<u></u>
SEVERITY	PEOPLE	ENVIRONMENT	COMPLIANCE	PROPERTY	PROCESS/PROJECT
CRITICAL	Multiple deaths from injury or illness; multiple cases of injuries involving permanent disability; or chronic irreversible illnesses.	Permanent loss of a public resource (e.g. drinking water, air, stream, or river).	Willful disregard for the rules and regulations.	Loss of multiple facilities or program components; (>\$5,000,000 total cost*)	Total breakdown identified resulting in loss/shut down of a process or project.
нібн	One death from injury or illness; one case of injury involving permanent disability; or chronic irreversible illnesses.	Long-term loss of a public resource (e.g., drinking water, air, stream, or river).	Major noncompliance that exposes the Lab to significant potential fines and penalties.	Loss of a facility or critical program component; (>\$5,000,000 total cost*)	Major breakdown identified resulting in the failure to attain the budget, schedule, key performance indicators or customer expectations.
MEDIUM	Injuries or temporary, reversible illnesses resulting in hospitalization of a variable but limited period of disability.	Seriously impair the functioning of a public resource.	Significant noncompliance that requires reporting to DOE or other authorities.	Major property damage or critical program component; (\$1,000,000 - \$5,000,000 total cost*)	Significant compromise to the attainment of the budget, schedule, key performance indicators or customer expectations which exposes process/project to potential failure if gap cannot be immediately resolved.
LOW	Injuries or temporary, reversible illnesses not resulting in hospitalization but with lost time.	Isolated and minor, but measurable, impact(s) on some component(s) of a public resource.	Programmatic noncompliance with the Lab's Work Smart set.	Minor property damage or critical program component; (\$50,000 - \$1,000,000 total cost*)	Minor breakdown or gap identified which does not result in significant compromise to the attainment of the budget, schedule key performance indicators or customer expectations; gaps can be resolved.
MINIMAL	Injuries or temporary illnesses requiring only minor supportive treatment and no lost time.	No measureable impact on component(s) of a public resource	Specific instance of a noncompliance with the Lab's Work Smart set.	Standard property damage or critical program component; (<\$50,000 total cost*)	Minor gaps identified which do not compromise the attainment of the budget, schedule, key performance indicators or customer expectations; gaps can easily be resolved.

Fermilab Quality Assurance Manual

12030TA-15

WARNING: This manual is subject to change. The current version is maintained on the ESH Section website.





### TABLE 2.

MISHAP PROBABILITY TABLE			
PROBABILITY DESCRIPTION			
Α	Could occur annually		
B Could occur once in two years			
С	Occurring not more than once in ten years		
D	Occurring not more than once in thirty years		
E	Occurring not more than once in one hundred years.		

# TABLE 3.

RISK ASSESSMENT CODE					
PROBABILITY					
SEVERITY	Α	В	С	D	E
Critical	1	1	1	2	3
High	1	1	2	3	4
Medium	1	2	3	3	4
Low	2	3	3	4	5
Minimal	3	4	4	5	5



# 7.0 Appendix B Definitions of Activities

- Director's Triennial ES&H (Environment, Safety & Health assessments)
  Assessment whose purpose is to determine how well the Laboratory is meeting its goals to maintain a safe work place, protect the environment, strive for the highest quality work, and comply with Laboratory requirements.
- Department of Energy (DOE) Headquarters Reviews
  Reviews conducted by DOE organizations at the headquarters level, i.e., Office of Science or
  Environment, Safety, and Health. The methods for conducting these reviews and the handling of
  any associated corrective and preventive actions that result from them are established by the
  sponsoring Office.
- Division/Section Head/Project Manager (D/S/P) Internal Assessment An assessment conducted entirely by D/S/P personnel and reported internally to the leadership head of the D/S/P to measure the degree of compliance with plans, DOE orders, FESHM or other directives from agencies of the federal and State government.
- D/S/P Management Walkthrough A less formal assessment conducted by senior management personnel.

#### • DOE Reviews

A review planned and conducted by DOE-FSO (Fermi Site Office). Results of these reviews may be considered when developing Fermilab's and D/S/P self-assessment reports. Findings from these reviews are formally transmitted to the Laboratory along with requests for corrective and preventive actions that must be addressed.

- Environment, Safety, Health and Quality (ESH&Q) Section Assessments
  Assessments conducted on an as-needed basis by the ESH&Q Section that are scheduled outside
  from the Tripartite Assessment process. Such supplemental assessments may be motivated by an
  incident, a perceived weakness in quality, a verification of effectiveness, an ESH&Q program, or by
  a new requirement. These assessments also include Quality Assurance Assessments.
- Formal ES&H investigation Investigations required by Fermilab's Work Smart set of standards, including Computerized Accident Investigation Reporting System (CAIRS) and Occurrence Reporting and Processing System (ORPS) investigations, as well as formal internally initiated investigations.
- Highly Protected Risk (HPR) Inspections ES&H inspections of buildings conducted by the Fire Protection Engineer and members of the assessed organization.
- Incident/Accident
  Work related event(s) in which an injury or ill-health (regardless of severity) or fatality occurred, or could have occurred.



### **Fermilab Quality Assurance Manual**

FESHM 12030TA January 2015

Notes: (1) An accident is an incident which has given rise to an injury, ill health or fatality.

- (2) An incident where no injury, ill health, or fatality occurs may also be referred to as a "near-miss", "near-hit", "close call", or "dangerous occurrence".
- (3) An emergency situation is a particular type of incident.

#### • Inspections/Walk-throughs –

An examination of a work area for the purposes of determining compliance to a specified requirement or standard, and usually results in simple corrections or remedial actions for identified items as opposed to corrective action planning, although corrective action items can be identified from these activities.

### Regulatory Agency Inspections

Inspection by agencies external to DOE including State and Federal agencies such as EPA, IEPA, and USDOT.

### • Third Party Audits/Assessment

Audits and/or assessments performed on the organization by agencies external to Fermilab.

### • Tripartite Assessment

A major component of Fermilab's ESH&Q's self-assessment program. The Tripartite assessment is performed and planned jointly by a D/S/C, the ESH&Q Section, and the DOE-FSO and led by a member of the organization being assessed.